

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8395

Bartle, C.J.

February 5, 2010

Shelley Murphy ("Ms. Murphy" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Ronald C. Murphy, Ms. Murphy's spouse, also submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Thomas S. Davidson, M.D. Based on an echocardiogram dated October 18, 2001, Dr. Davidson attested in Part II of Ms. Murphy's Green Form that she suffered from moderate mitral regurgitation³ and an

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contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Davidson also attested that claimant had moderate aortic regurgitation. As Ms. Murphy's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

abnormal left atrial dimension.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$497,928.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Charles F. Dahl, M.D., stated that "[m]oderate mitral regurgitation was noted with the jet filling 20% of the [left atrial] area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In September 2002, the Trust notified Ms. Murphy that her claim had been selected for audit.⁷ In response, claimant

5. Dr. Davidson also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for Level II benefits, the only issue is claimant's level of mitral regurgitation.

7. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. and VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit only claimant's level of mitral

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submitted expert reports by Dr. Davidson and Amjad Iqbal, M.D. Dr. Davidson stated that he "found the mitral regurgitant jet to be $4.34/21.53=20.1\%$. This is consistent with moderate mitral regurgitation." Likewise, Dr. Iqbal found that claimant's echocardiogram "reveals moderate degree of mitral regurgitation, regurgitant jet area to left atrial area ratio of 20%."

In October 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists.⁷ In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Davidson's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Irani stated that claimant's "RJA [was] overtraced into [left ventricle] - ratio is <20%."

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Murphy's claim. Pursuant to the Audit Policies and

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regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

8. After the Trust forwarded the claim to Dr. Irani, claimant submitted another expert report, this one signed by Dr. Dahl. Therein, Dr. Dahl confirmed his initial finding of moderate mitral regurgitation by stating that: "The mitral regurgitation jet occupies 20% of the left atrial area. The jet is present two-thirds of the way through systole and extends half-way to the back of the left atrium. In addition, the regurgitation area is greater than 4 cm, again supporting moderate mitral regurgitation."

Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § IV.C.⁹ The Trust then applied to the court for issuance of an Order to show cause why Ms. Murphy's claim should be paid. On February 12, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2749 (Feb. 12, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 9, 2003. Claimant submitted a sur-reply on January 6, 2005. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims

9. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Murphy's claim.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two (continued...)

after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's representation that Ms. Murphy had moderate mitral regurgitation. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Murphy submitted declarations by Dr. Davidson and Dr. Iqbal. Each declaration attached reports that were initially provided in response to the Trust's notification that Ms. Murphy's claim was being sent to audit. In their declarations, Dr. Davidson and Dr. Iqbal

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outstanding experts who take opposite positions" is proper. Id.

reaffirmed their previous findings of moderate mitral regurgitation. Claimant argues that she has established a reasonable medical basis for her claim based on the detailed findings of her physicians. According to claimant, "reasonable medical basis" is a fluid term, which incorporates inter-reader variability and "includes the possibility of up to 10% variation between board certified cardiologists of the same level of certification."¹¹ Claimant also argues that: (1) the auditing cardiologist's opinion is inadmissible ipse dixit¹² because Dr. Irani fails to explain the basis for his opinion that there is no reasonable medical basis for the attesting physician's Green Form representation that claimant suffered from moderate mitral regurgitation; and (2) the Trust's conduct with respect to its interpretation and application of the Audit Policies and Procedures violates her due process rights because it deprives her of Matrix Benefits without the opportunity to be heard in a meaningful manner.

In response, the Trust argues that claimant cannot meet her burden of proof simply by proffering opinions from additional physicians. The Trust also asserts that Dr. Irani complied with the Settlement Agreement in the manner in which he reviewed

11. In support, claimant submitted a partial transcript of testimony from John Dent, M.D., the Trust's expert during the September 2002 hearings, which ultimately resulted in the court's issuance of PTO No. 2640 (Nov. 14, 2002).

12. Ipse dixit is Latin for "he himself said it." It stands for the proposition that something is asserted but not proved. Black's Law Dictionary 847 (8th ed. 2004).

claimant's echocardiogram. Further, the Trust contends that Dr. Irani found that there was no reasonable medical basis for Dr. Davidson's finding of moderate mitral regurgitation because claimant only had mild mitral regurgitation. In addition, the Trust disputes claimant's characterization of the reasonable medical basis standard. Finally, the Trust argues that it afforded claimant due process.

In her sur-reply, Ms. Murphy argues that her claim is supported by a reasonable medical basis because Dr. Davidson identified the presence of moderate mitral regurgitation at a specific frame, 5:35:44, of her echocardiogram tape.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for Dr. Davidson's finding of moderate mitral regurgitation. Specifically, Dr. Abramson stated that:

In reviewing the transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation. In addition to my visual estimate, I measured the mitral regurgitant jet in five different cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $0.97 \text{ cm}^2/21.79 \text{ cm}^2$, $2.38 \text{ cm}^2/22.81 \text{ cm}^2$, $2.30 \text{ cm}^2/21.28 \text{ cm}^2$, $1.85 \text{ cm}^2/19.66 \text{ cm}^2$, and $1.98 \text{ cm}^2/17.69 \text{ cm}^2$. These ratios are 4.4%, 10.4%, 10.8%, 9.4% and 11.2%, all of which are considerably less than 20% which is consistent with mild mitral regurgitation. The mitral regurgitant jet which the sonographer traced on the tape includes non-regurgitant flow which makes the area, and thus the RJA/LAA ratio erroneously larger than the true ratio. This accounts for the difference between the ratios the Attesting Physicians cite and the ones that I measured.

In summary, it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that this patient has moderate mitral regurgitation. This patient has only mild mitral regurgitation.

Claimant submitted a response to the Technical Advisor's Report. Claimant argues that: (1) Dr. Abramson failed to apply the reasonable medical basis standard and instead substituted her finding of mild mitral regurgitation for that of Dr. Davidson's finding of moderate mitral regurgitation; (2) inter-reader variability accounts for the difference between Dr. Abramson's finding and that of Dr. Davidson's finding; and (3) Dr. Abramson merely provides "an ipse dixit conclusion" without explaining why there was no reasonable medical basis for Dr. Davidson's finding.

After reviewing the entire Show Cause Record before us, we find claimant's arguments are without merit. First, we disagree with claimant that Dr. Irani's and Dr. Abramson's conclusions are unsupported. To the contrary, Dr. Irani specifically explained that claimant's "RJA [was] overtraced into [left ventricle] . ." Likewise, the Technical Advisor's Report contained a detailed explanation of how Dr. Abramson reached her conclusion. Dr. Abramson took five separate measurements of claimant's level of mitral regurgitation, all of which were significantly less than the required threshold under the Settlement Agreement. Moreover, Dr. Abramson specifically stated

that the jet traced by the sonographer included non-regurgitant flow, which made the "RJA/LAA ratio erroneously larger." These findings are more than sufficient to support Dr. Irani's and Dr. Abramson's conclusions that there was no reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation.¹³

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO

13. For this reason as well, we reject claimant's assertion that Dr. Irani's and Dr. Abramson's respective conclusions constitute ipse dixit and that Dr. Abramson purportedly substituted her opinion for that of the attesting physician.

No. 2640 at 9-13, 21-22, 26. Here, Dr. Irani and Dr. Abramson respectively concluded, and claimant does not dispute, that claimant's "RJA [was] overtraced into [left ventricle]" and the mitral regurgitant jet "includes non-regurgitant flow." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

Further, claimant's argument that inter-reader variability accounts for the discrepancy between the measurements of her physicians and Dr. Abramson must fail. As we previously stated, "[b]ased on the Singh grading system, the Settlement Agreement provides the basis for determining a claimant's level of mitral regurgitation. The concept of inter-reader variability is encompassed in this standard." PTO No. 6824 at 10 (Dec. 29, 2006). In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrates an RJA/LAA ratio of at most 11.2%. Adopting claimant's argument on inter-reader variability would expand the range of moderate mitral regurgitation by 10% and would allow a claimant to recover Matrix Benefits with an RJA/LAA ratio as low as 10%. This result would render meaningless this critical provision of the Settlement Agreement.

We also reject claimant's assertion that the use of a single frame from her echocardiogram demonstrates a reasonable medical basis for her claim. We have previously stated that "'[o]nly after reviewing multiple loops and still frames can a

cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" PTO No. 6897 at 7 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). As claimant has not established that the still frame offered in support of her claim is representative of her level of mitral regurgitation, claimant has failed to establish a reasonable medical basis for her claim. This is especially true where, as here, both Dr. Irani and Dr. Abramson identified specific deficiencies with the tracings found on claimant's echocardiogram tape.

Finally, claimant's argument that the Trust deprived her of due process is without merit. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Policies and Procedures § VI.D. The audit and show cause process, as approved by this court, comply with due process requirements, as claimant has had notice and an opportunity to present her evidence in support of her claim.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Murphy's claim for Matrix Benefits and the derivative claim submitted by her spouse.